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RE: Technical Memorandum - Proposed Reference Blood Lead Data
for Use in the Butte Health Study

Dear Ladies and Gentlemen:

Enclosed for your review is the technical memorandum for Proposed Reference Blood Lead Data for Use in the Butte Health Study ("technical memorandum"). Butte-Silver Bow County (BSB) and Atlantic Richfield Company (AR), the Group 1 responsible parties, have been working together and in consultation with the U.S. Environmental Protection Agency (EPA), the Montana Department of Environmental Quality, the Agency for Toxic Substances and Disease Registry, members of a Health Studies Citizens' Advisory Committee, and a representative of the Citizens Technical Environmental Committee to prepare the enclosed technical memorandum. The technical memorandum satisfies the first deliverable identified in the Public Health Study Remedial Design Work Plan for the Butte Priority Soils Operable Unit, Phase 1 Study, which was approved by EPA on June 3, 2013.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Dan Powers, R.S.

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Technical Memorandum
Proposed Reference Blood Lead Data for Use in the Butte Health Study

Butte, Montana

Prepared by:
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Seattle, Washington

Date:
August 2013

Project Number:
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ENVIRON

Contents

1 Introduction

As detailed in the U.S. Environmental Protection Agency (EPA)-approved Butte health study work plan, the primary study objective to be addressed by the health study is the review and evaluation of available Residential Metals Abatement Program (RMAP) data that have been collected to date in order to objectively document the efficacy of the RMAP and identify any areas where improvement to activities conducted via the RMAP may be needed to effectively identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community. To address the study objective, the approved study plan focuses on analyses of the more than ten years of blood lead data compiled by BSB to assess blood lead levels (BLLs) in Butte children[1]. More specifically, examination of the blood lead data will be conducted to assess whether changes in community-wide exposures are evident based on the following lines of evidence:

- Statistically significant differences in BLLs across neighborhoods within the Butte community, measured in conjunction with the RMAP, are reduced relative to differences documented pre-RMAP differences in BLLs across these same neighborhoods.

and/or

- The distribution of BLLs in the Butte community and in a reference population are similar over the same period evaluated.

As discussed in the EPA-approved work plan, if the lines of evidence support a finding that improvements to the RMAP are necessary to identify and mitigate potentially harmful exposures to sources of lead, arsenic and mercury in the Butte community, then response actions appropriate to addressing identified RMAP deficiencies will be investigated and proposed.

In support of the second line of evidence, this technical memorandum proposes a reference blood lead data source for use in comparison to the Butte blood lead data. Examination of the comparability of factors that may influence BLLs across datasets is an important consideration for selection of a reference blood lead data source. Such factors include demographic characteristics (e.g., gender, age, income level, etc.), age of housing stock within the community, blood lead testing and analytical methodologies, as well as whether or not a potential reference data set has a Superfund site history similar to Butte. The intent of this technical memorandum is to detail the process used to assess a variety of potential reference data sources and summarize the outcome of that process leading to a recommendation for use of a primary reference data source to best support comparisons of the distribution of BLLs in the Butte community and in a reference population over the same periods given consideration of such factors.

[1] As noted in the approved work plan, young children (ages 1 to 5 years) are most susceptible both to lead exposures and also to adverse effects of lead. Numerous studies across the U.S. have demonstrated that this population has the highest blood lead levels. Therefore, focusing on this population provides the most effective means of detecting any elevation of lead exposures in affected neighborhoods. This focus on young children is also protective of all persons including older children and adults.

Two categories of data sources were considered to identify potential reference blood lead data sets. One source investigated was Montana communities with various characteristics comparable to Butte (e.g., size, urbanization, age of housing stock, socioeconomic status) that also have sufficient blood lead data from some or all of the years for which Butte data are available. The second source category was national blood lead data from the National Health and Nutrition Examination Survey (NHANES). For investigation of this source, our analysis involved determining the feasibility of adjusting available NHANES data to create an NHANES-based reference population with characteristics similar to Butte. In conducting research on these sources, it was understood that identification of one or more reference data sources that could be matched perfectly to the Butte data with respect to all factors that may influence BLLs would not be feasible. Both kinds of data sets were found to offer different advantages and disadvantages; however, community-based data are subject to significant limitations in the availability of data for the time periods and ages of interest, whereas the NHANES database was not subject to these limitations. Therefore, we recommend use of the NHANES database as the primary blood lead data reference source for comparison to the Butte community in the health study. Additional comparative analyses using subsets of Butte data with some of the community data sources may also be useful for interpreting the distribution of BLLs in Butte. Such supplemental analyses will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds.

This memorandum summarizes the processes used, possible reference data identified, and details the rationale for proposed use of the NHANES blood lead data source. Proposed statistical approaches for study data analyses to support examination of Butte blood lead data in comparison to appropriate reference population data will not be finalized until approval of this technical memorandum and the proposed primary reference data source by EPA in consultation with the Montana Department of Environmental Quality. However, in anticipation of such approval, this memorandum details specific data adjustment and weighting steps that would be necessary to ensure comparability of the datasets, particularly with regard to those factors that are known to affect BLLs. Given the importance of these factors in selection of appropriate blood lead reference data, this memorandum is organized with an overview of these factors first, followed by findings of our research and evaluation of specific data sources leading to recommended use of the NHANES data source for development of the reference data sets.

2 Consideration of Factors Influencing the Comparability of Blood Lead Datasets

This section provides a review of factors known to correlate with and/or to affect BLLs as well as those which may affect interpretation of blood lead measurements. Examination of the comparability of these factors across datasets is a crucial element to guide our reference population selection and study design. Specifically, an assessment of factors that may influence the comparability of different blood lead datasets must include consideration of factors that could be contributing to an observed effect. It is also important to characterize the sampling and analytical methods used to measure BLLs and the associated detection limits as these may also influence meaningful comparison of two blood lead datasets.

In assessing lead exposures in Butte, we start by characterizing the population for whom we have data and then identifying additional factors that may affect BLLs in that population. The majority of the data in the Butte database are from young children between 12 and 60 months of age. The majority of sample dates range from late 2002 through late 2011. The primary sampling method was finger stick/capillary tube with an analytical detection limit of 1 µg/dL. Additional key characteristics for this population include racial/ethnic profile (predominantly non-Hispanic white) and house age (many neighborhoods with very old housing). The ways in which these and other factors may affect the comparability of potential reference blood lead datasets to Butte data are described below.

2.1 Comparability Based on Sampling and Analytical Methods

A critical factor to examine in selecting reference data is the analytical method used and the associated detection limits. Different whole blood sampling methods (i.e., venous sample vs. finger stick with capillary tube or filter paper) and analytical methods are used in different programs. A key concern with the use of finger stick sample collection vs. venous sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Consequently, data collected by finger stick is likely to be biased high compared with data collected by venous samples.

Detection limits may vary widely and reproducibility may also vary. Detection limits have declined over time during the past few decades; however, current regulations still allow ±4 µg/dL laboratory error in blood lead proficiency testing programs, and variations in test results of ±2 µg/dL are normal and are well within the acceptable lab error (Binns et al. 2007, ACCLPP 2012). The lowest detection limits are typically associated with venous samples and graphite furnace atomic absorption spectrometry (GFAAS) or inductively coupled plasma mass spectrometry (ICP-MS).

For blood lead analyses for the NHANES, detection limits have been 0.3 µg/dL or less over the past decade, whereas most capillary samples are analyzed by methods with a detection limit of 1 µg/dL. A kit called the LeadCare II point of care device, also being used by some programs, has a detection limit of 3 µg/dL. As BLLs have continued to decline, use of higher detection limits results in large numbers of samples falling below the detection limit, and may prevent accurate characterization of population blood lead distributions and means. Disparities in detection limits may also affect population comparisons. For the purposes of this study, data collected using the LeadCare II device is not useable because the detection limit is too high to allow for an assessment of the blood lead distribution in the datasets.

2.2 Comparability Based on Factors Influencing Blood Lead Levels

Blood lead levels have declined precipitously in all U.S. populations since the 1970s with implementation of the ban on lead additives in gasoline and in paint, along with control of lead sources in plumbing, canned foods and other sources. Nevertheless, a variety of factors continue to be associated with higher BLLs. These include demographic factors such as gender, age and race/ethnicity, as well as a variety of socioeconomic factors such as income level and maternal education.

2.2.1 Sample Year, Age and Gender

Two primary factors to be considered in designing lead exposure comparison studies are the year in which the sample was collected and the age of the subject. Blood lead levels may also vary by gender, but this is not currently a significant factor for all age cohorts based on national data.

As noted above, BLLs have declined over the past few decades, and continue to decline, albeit at a slower rate. It has also been consistently observed in the U.S. that on average young children between the ages of 1 and 3 years have the highest BLLs. These trends are both illustrated in Figure 1, which shows the continued decline in BLLs in successive birth cohorts, as well as the decline in BLLs as each birth cohort gets older. Consequently, comparisons of BLLs must ensure that the subject populations are matched in terms of sample year and subject age.

Much available blood lead data focuses on young children because their BLLs are higher than other age groups. Preliminary analyses of the Butte dataset confirm that BLLs have been trending down over the period from late 2002 to late 2011, and that BLLs are higher in 1 to 5 year old children compared with older children and adults (Figure 2).

Blood lead levels also vary by age within the 1 to 5 year old cohort. Even as BLLs have declined over time, the ages with peak average BLLs have consistently remained 12 to 36 months. This factor indicates that it will be necessary to ascertain if a reference dataset has the same age structure as the Butte dataset. In contrast, during the past ten years in the U.S. there have not been consistent gender-related differences in BLLs in young children. Figure 3 illustrates these factors for a national dataset for two time periods, i.e., from 2003 – 2006 and from 2007 - 2010.

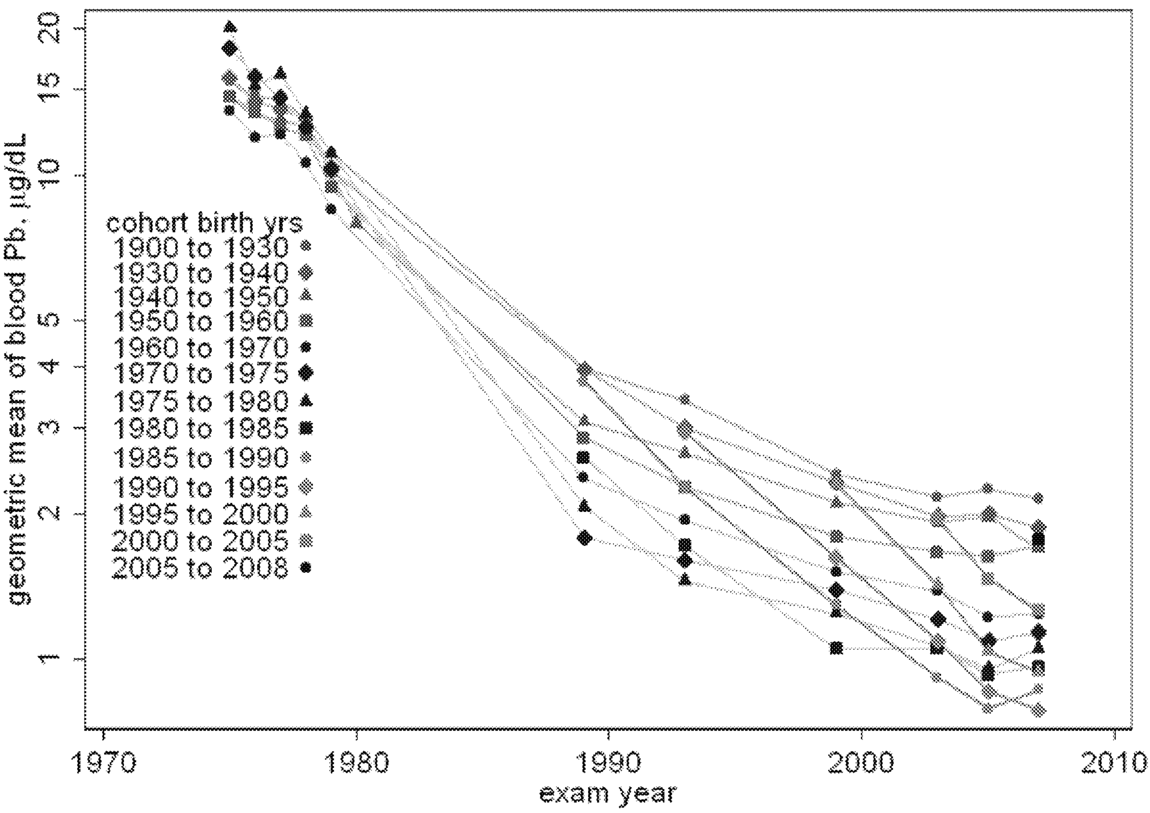


Figure 1. Decline in Blood Lead in Different NHANES Birth Cohorts (source: USEPA 2013a)

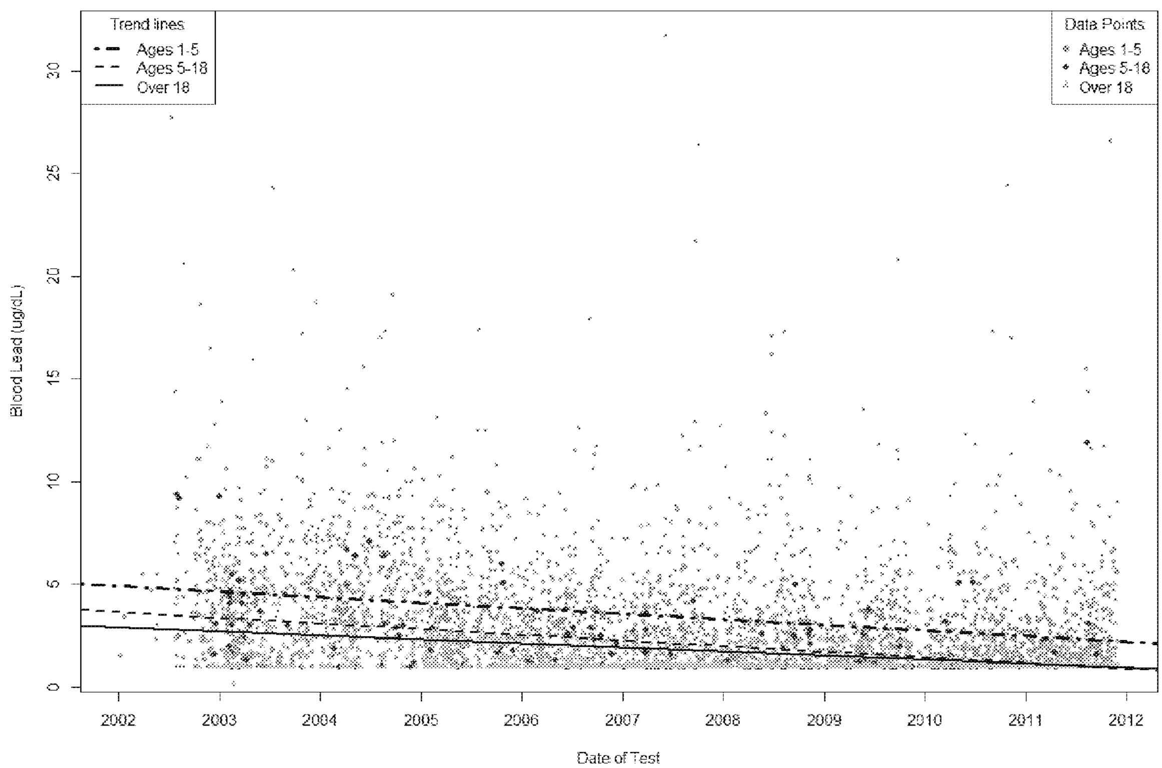


Figure 2. Butte Blood Lead over Time by Age Group for Individuals Aged 1 Year or Older (Excluding Lead Care II Results)

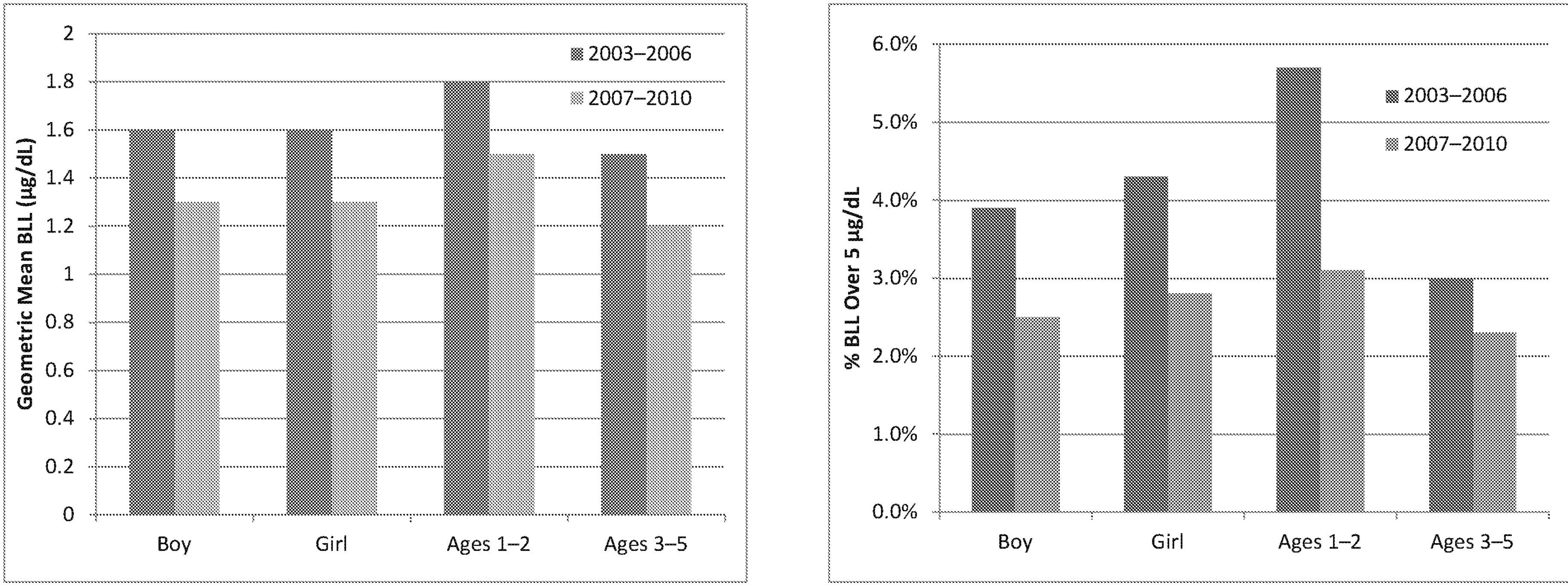


Figure 3. Blood Lead by Gender and Age Group from U.S. Children Ages 1 to 5 (From U.S. Centers for Disease Control and Prevention [CDC] Morbidity and Mortality Weekly Report April 5, 2013)

2.2.2 Demographic and Socioeconomic Factors

Demographic and socioeconomic factors such as race/ethnicity, income level, educational attainment of parents and housing status have been correlated with BLLs in children and are important in identifying appropriate comparison communities for the Butte health study (Sargent et al. 1995, CDC 2000, Gee and Payne-Sturges 2004, CDC 2013a, Jones et al. 2009). BLLs also are known to vary with season. The relative importance of these factors may be expected to vary over time. For example, while the difference in BLLs between non-Hispanic black children vs. non-Hispanic white children is still significant, the magnitude of the difference has decreased substantially over time (CDC 2013a). Jones et al. (2009) and CDC (2013a) provide summaries of trends in the primary demographic and socioeconomic factors for U.S. children from 1988 through 2010. Factors considered during identification of possible reference populations for Butte are described below.

Race/Ethnicity – As described above, race continues to be a significant risk factor for elevated BLLs with the highest levels on average reported for non-Hispanic black children. Figure 4 illustrates race and ethnicity differences in geometric mean BLLs and BLLs greater than 5 µg/dL for a national dataset for two time periods during the past decade. As shown in Figure 4, average BLLs are higher in non-Hispanic black children and the percent of these children with BLLs greater than 5 µg/dL is more than twice as high as the percent of white, non-Hispanic and Mexican children with elevated BLLs.

Poverty status – Children living in poverty have higher BLLs compared with children in wealthier households. Two measures are used in national studies to assess poverty status: the poverty to income ratio and Medicaid enrollment. The poverty to income ratio or PIR is the total family income divided by the federal poverty threshold specific to family size, year and state of residence. Figure 5 compares geometric mean BLLs and BLLs greater than 5 µg/dL for children from low income households (defined as a PIR of less than 1.3) with those from higher income households, and also compares BLLS for children enrolled in Medicaid with those not enrolled. Both of these measures of poverty status are associated with higher mean BLLs and substantially higher percent of children with BLLs greater than 5 µg/dL

House age – Older housing is associated with higher BLLs for a variety of reasons, including the historical use of exterior and interior paint with added lead and higher frequency of lead plumbing lines and fixtures in older homes. Lead paint is primarily a concern when the paint condition deteriorates, so poverty status and living in rental housing are related factors that may contribute to greater exposure to lead pain in older housing. Lead content of paint was reduced over several decades prior to its ban in 1978. Figure 6 shows the influence of house age on average and elevated BLLs for several categories of house age. As can be seen from this figure, the percent of children with elevated BLLs is markedly higher for those living in houses built prior to 1950.

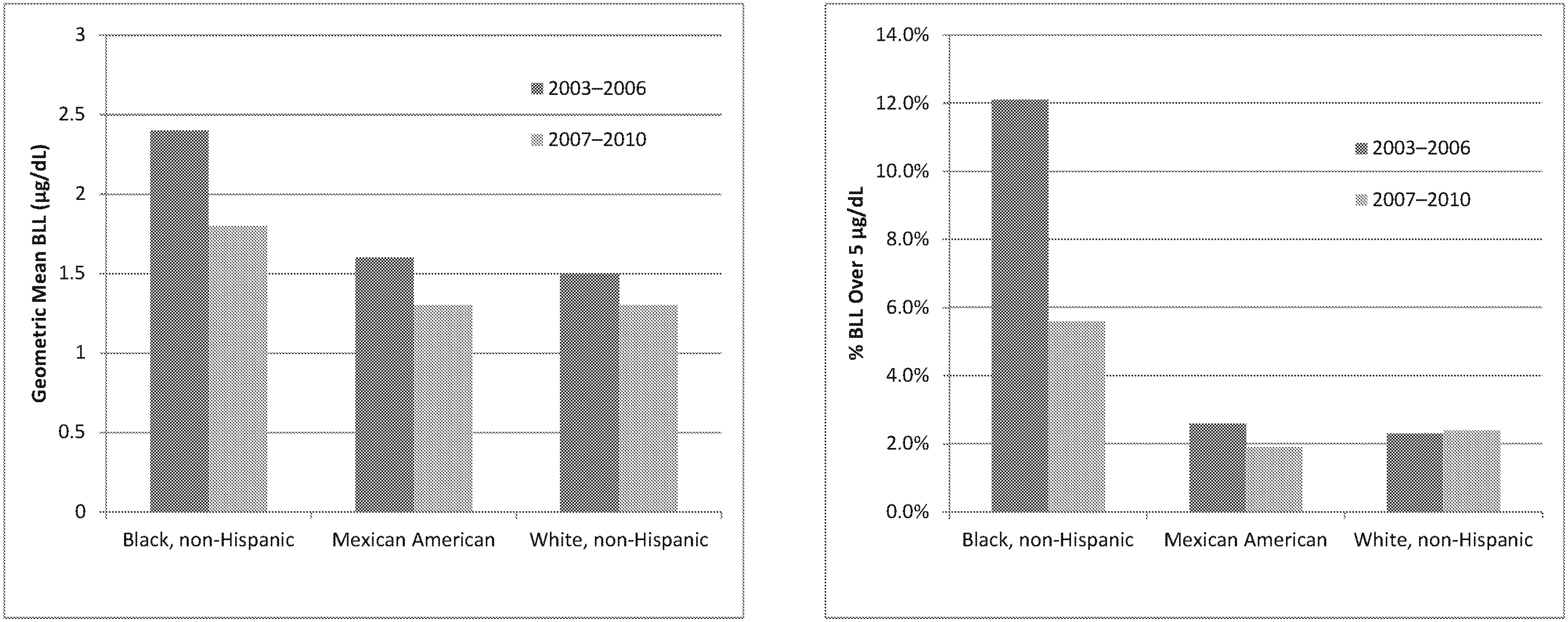
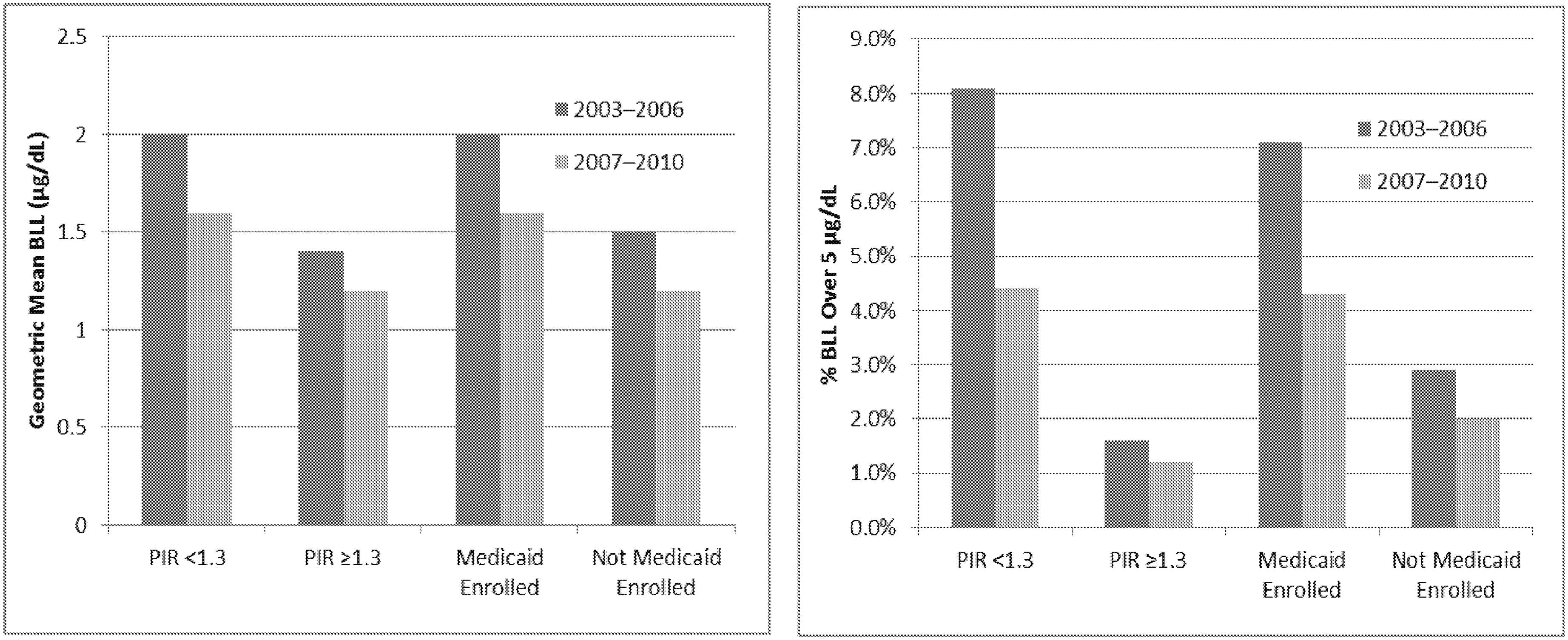


Figure 4. Blood Lead by Race/Ethnicity from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)



PIR = Total annual family income/
Federal poverty threshold specific to family size, year, and state of residence.

Figure 5. Blood Lead by PIR and Medicaid Status from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)

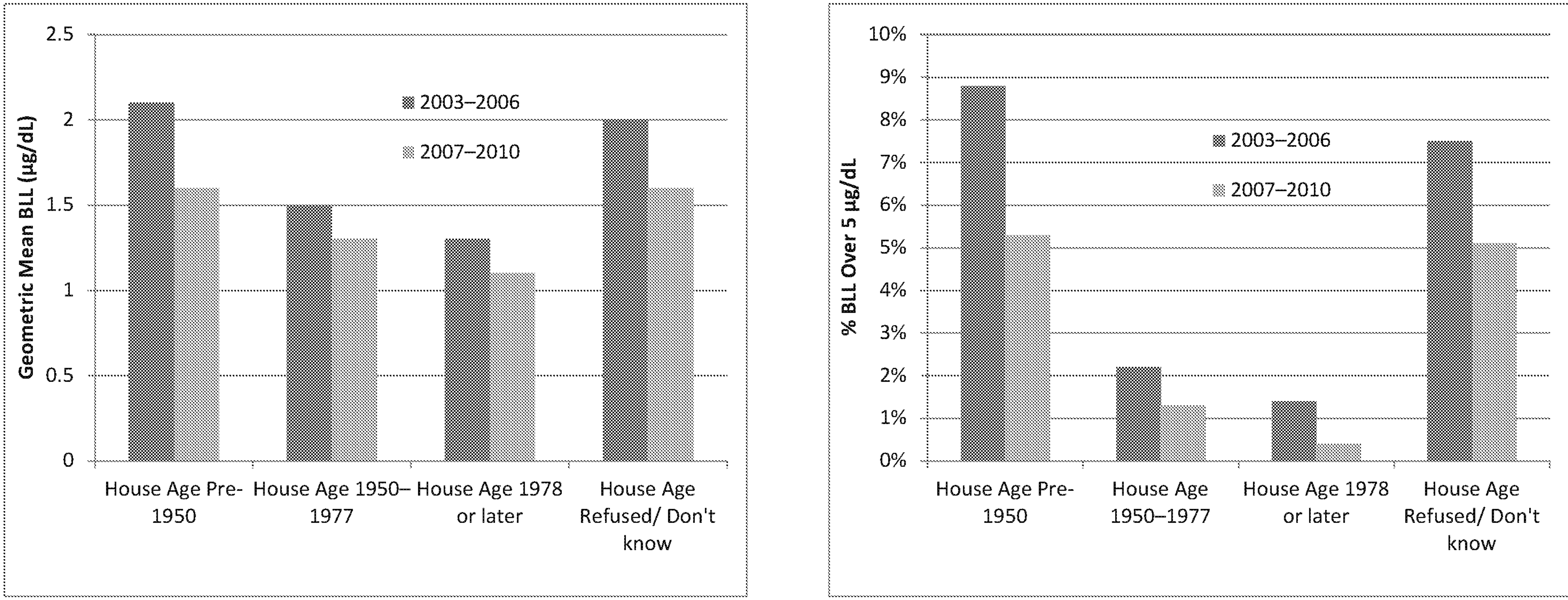


Figure 6. Blood Lead by House Age from U.S. Children Ages 1 to 5 (From CDC Morbidity and Mortality Weekly Report April 5, 2013)

Season – BLLs in young children have long been known to be highest in summer and early autumn. This pattern has been assumed to be associated with greater exposure to soil containing lead, due to more time spent outside and to more soil tracked and blown into the house during the summer months. A recent study of BLLs in Detroit area children has confirmed that this pattern still occurs; with late summer BLLs averaging between 11% and 14% higher than BLLs measured in January (Zahran et al. 2013). A preliminary analysis of the Butte dataset suggests that the variation may be even greater among Butte children.

All of the factors described above have been shown to have a substantial impact on BLLs, and are evaluated in the identification of a reference population.

3 Identification of Possible Reference Communities

This section includes a description of the methods used to identify possible reference communities and methods for acquisition of blood lead data, followed by summaries of key communities that had relevant blood lead data, including Flathead, Gallatin, Lewis and Clark and Yellowstone Counties in Montana, and Lake County, Colorado and Shoshone County, Idaho. Communities are identified as counties because data were generally managed by and available from county health departments.

3.1 Methods for Identifying Reference Communities

Identification and evaluation of publically-available blood lead datasets for Montana communities and other communities in the mountain west considered similarities between Butte and potential reference communities with regard to the following:

- urbanization level,
- demographics,
- socioeconomic characteristics,
- time periods of blood lead data sampling,
- ages of individuals represented by blood lead data.

Differences in level of urbanization have been shown to relate to differences in health statistics. For example, death rates generally increase with decreasing urbanization across multiple age groups, for both genders (Ingram and Franco 2012). It is thought that this and other observed health disparities between urban and rural communities reflect differences in demographic, economic, physical, social, and environmental characteristics, in addition to differences in access to and characteristics of available health care resources (Ingram and Franco 2012).

To facilitate the examination of urbanization level impacts on health, the National Center for Health Statistics (NCHS) developed the 2006 Urban-Rural Classification Scheme for Counties, which assigns counties to one of four metropolitan or two nonmetropolitan urbanization categories. There are 56 counties in Montana, including Butte-Silver Bow County. Due to the level of effort involved with online and phone research to identify the existence and characteristics of blood lead data for each of these counties and/or individual communities within them, we first narrowed the potential list of communities by comparable urbanization level. The NCHS classifies Silver-Bow County as a “micropolitan” area because it contains at least one urban cluster of 10,000 – 49,999 inhabitants present in a nonmetropolitan area (Ingram and Franco 2012). Other Montana counties designated as micropolitan include Flathead, Gallatin, Hill, Jefferson, and Lewis and Clark (Ingram and Franco 2012).

The NCHS designations provide more classifications for metropolitan than nonmetropolitan counties and the focus is on population size of urban clusters, independent of economic base and other factors that may influence health characteristics, such as housing stress and type of economy. To further explore nonmetropolitan counties with similar characteristics, additional refinement of rural classifications was sought.

The U.S. Department of Agriculture Economic Research Service (ERS) provides rural classification codes for the six NCHS-designated micropolitan counties, shown in Table 1 (USDA 2009, 2013). The ERS 2013 Rural-Urban Continuum Code (RUCC) further classifies nonmetropolitan counties according to population density as well as proximity to metropolitan areas, a measure of urban influence. Of the six NCHS-designated micropolitan counties, four counties, including Silver Bow, are similarly designated as RUCC code 5, nonmetropolitan counties with an urban population of 20,000 – 49,999, not adjacent to a metropolitan area[2]. The nonmetropolitan counties with similar urbanization to Silver Bow County, i.e., Flathead, Gallatin, and Lewis and Clark, were the focus of further characterization to assess the potential for comparability of factors that may influence blood lead data and also for availability of blood lead data.

Demographic and socioeconomic information specific to Silver Bow, Flathead, Gallatin, and Lewis and Clark Counties was obtained from the ERS and U.S. Census Bureau to characterize factors potentially influencing BLLs.

ERS assigns typology codes to each county to identify differences in economic and social characteristics. ERS codes for economic dependence, housing stress, and nonmetropolitan recreation status, shown in Table 1, relate to factors that can directly or indirectly influence blood lead, and may be considered in identifying strengths and weaknesses of potential reference populations. U.S. census demographic (e.g., gender and age distributions) and socioeconomic (e.g., educational attainment, income, and poverty) data are provided in Table 2 to further characterize potential reference population characteristics. In addition, Table 3 provides housing data obtained from the U.S. census, which represent an important factor associated with lead exposure in children.

Consideration of the urbanization level, demographics, and socioeconomics helps us identify and characterize communities that may be suitable reference populations for the Butte health study. Together, the NCHS, ERS, and census information provide us with quantified measures for cross-community comparisons that allow us to best match non-mining-related risk factors influencing BLLs. However, identified communities also must have publicly-available blood lead data to compare with Butte BLL data. Also, if blood lead data are identified, consideration of the time period during which the data were collected, collection and analytical method, and age range of the sampled population also must be evaluated for comparability to the Butte database.

3.2 Methods for Acquisition of Blood Lead Data

Following identification and characterization of counties with levels of urbanization similar to Silver Bow County as Flathead, Gallatin, and Lewis and Clark Counties, we sought to identify sources of blood lead data in each of these counties. Initially, the Montana Department of Public Health and Human Services (MDPHHS) was contacted in an effort to access state-wide data from which to obtain blood lead data for the target counties. However, it was reported that no state-wide blood lead statistics are publicly available (Cannon 2013, Helgerson 2013, Zanto

[2] Hill County is classified as a nonmetro county with an urban population of 2,500-19,999 not adjacent to a metro area; Jefferson County is classified as completely rural or less than 2,500 urban population not adjacent to a metro area.

2013). Like many other states, Montana has lacked funding for enforcement of reporting and centralized management and storage of blood lead data for Montana residents and little data is voluntarily reported to the state. In addition to few resources available to provide testing at the county and state levels, it was reported that many physicians are not recommending blood lead testing because lead exposure is not viewed as a current concern for most children under the age of six (Cannon 2013).

As discussed in the community summaries in the following section, lack of resources was often cited as a limitation to providing access to blood lead data, as well as being a limitation for general recording, storage, and management of data that is received from laboratories and health practitioners. The absence of Montana blood lead monitoring data is confirmed by the CDC's Childhood Lead Poisoning Data, Statistics, and Surveillance Program, which includes tested and confirmed elevated BLLs by year for children up to age 7 years beginning in 1997. Such summaries are provided for many states, but not for Montana (CDC 2013b). Similarly, other nearby states do not report blood lead data to the CDC, including Idaho, Wyoming, Colorado, North Dakota, and South Dakota, among others. Thus, finding blood lead data for comparable communities in neighboring states also presents a challenge. Once it was determined that a state-wide database could not be queried, we contacted county- and city-level organizations and/or agencies that would potentially collect and store child blood lead data.

In addition to seeking out local blood lead data sources, we opportunistically followed up on leads provided during conversations with MDPHHS staff, such as summary data for the 2012 Healthy Homes Study conducted by MDPHHS and focused collection efforts associated with Superfund clean-up in Butte, Libby, and East Helena, Montana. In such cases, we followed up on leads even if the data pertained to a county not previously identified as having a similar level of urbanization (i.e., Libby - Lincoln County), incompatible sample years (i.e., Healthy Homes Study participant counties), or influence of lead-emitting industrial sources (i.e., East Helena – Lewis and Clark County). Some summary data were obtained in this manner; data that are potentially suitable for use are described in the following community summary section.

Outside Montana, we were directed to the state of Colorado's Environmental Public Health Tracking Childhood Lead Poisoning Indicator Data, which includes summary blood lead testing information for children born between the years 2008 and 2011 and tested prior to their third birthday. The online database provides query results only for screening rate, number of children with confirmed and unconfirmed BLLs greater than 10 µg/dL, and number of children with BLLs less than 10 µg /dL. The raw blood lead data underlying these testing statistics are not readily available online. We contacted the Colorado Department of Public Health and Environment in an effort to obtain these data but were informed that data are not stored in a format that can be easily shared and there are no available resources that can be dedicated to manually retrieving data and/or removing confidential information (Kuhn 2013). Instead, we were referred to staff at the Lake County Blood Lead Program, due to the existence of a long-term blood lead surveillance program associated with the California Gulch Superfund Site near Leadville. Data obtained from Lake County are described in the following community summary section.

3.3 Community Summaries

A summary of demographic and socioeconomic characteristics, available blood lead data obtained from county and local-level organizations, and data suitability is provided for Butte-Silver Bow and each focus county, i.e., , Flathead, Gallatin, and Lewis and Clark. In addition, community profiles are provided where blood lead data were opportunistically obtained for communities outside the focus counties. These additional areas include Yellowstone County (Billings), Montana, plus Lake County, Colorado, and Shoshone County, Idaho. Blood lead data also were explored for Montana Healthy Homes Study participant counties, Globe, Colorado, and Rocky Mountain Arsenal, Colorado but no useful data were obtained from these locations; therefore, community summaries are not provided.

3.3.1 Butte-Silver Bow County, Montana

To assess the suitability of other Montana communities for comparison with Butte, we must first understand Butte economic, demographic, and social characteristics. These characteristics change over time, including over the study period ranging from 2002 to 2011. But, for the purpose of evaluating comparison communities, only more recent census (U.S. Census 2013) and ERS (USDA 2009, 2013) data are evaluated and presented in Tables 1 to 3.

Silver Bow County is home to roughly 34,000 people, 33,000 of whom live in Butte, and nearly 6 percent of County residents are under the age of 5 years. Ninety percent of Butte-Silver Bow residents have earned their high school diploma or equivalency and the median household income is roughly $40,000. In Butte-Silver Bow County, 16 percent of people live below the poverty level, which was defined as an annual income of $22,314 for a family of four in 2010 (U.S. Census 2011). The percentage of people living in poverty is higher in Butte-Silver Bow County (16 percent) than in Montana (14.6 percent) or the U.S. (14.3 percent) (U.S. Census 2013). Additionally, 40 percent of families with children less than five years old within Butte have incomes below the poverty level (U.S. Census 2013). The area addressed by the RMAP, which is the subject of this initial health study, includes the areas within Butte that have the highest percentages of families with incomes below the poverty level.

ERS does not classify Silver Bow County as a housing stress area, which would indicate that 30 percent or more of homes had one or more of the following conditions: incomplete plumbing or kitchens, cost 30 percent or more of occupants' income, and/or more than one person in residence per room (USDA 2009). Nearly half of Silver Bow County's total housing stock (16,675 units) was constructed prior to 1949 and roughly 80 percent of Butte housing was constructed prior to the ban of lead in paint in the late 1970's. Of the total housing units, 35 percent are not owner-occupied. Non-owner occupied housing (i.e., rental units) typically represents homes that are less likely to be maintained in good repair, which can be a concern when lead-based paint and plumbing are present (Sargent et al. 1995, Jacobs et al. 2002, Lanphear 2005).

Since 1989, the CDC has identified Medicaid-eligible children between the ages of 1 and 5 years as having an increased risk of lead exposure and targeted Medicaid-eligible children for preventive and screening measures, including blood lead testing (CDC 2009). Enrollment in Special Supplemental Nutrition Program for Women, Infant, and Children (WIC) and/or Head

Start is used as a proxy for Medicaid-eligible children and often, a partnership between CDC and WIC and/or Head Start is formed to facilitate blood lead screening and reporting to CDC.

In the Butte-Silver Bow County area, blood lead data are available for WIC-enrolled infants and children up to age 5 years as well as pregnant women for the years 2002 to 2011. The County health department has created a database to facilitate evaluation of blood lead data for the Butte health study, and will provide between 150 (2002) and nearly 500 results (2011) collected annually. Most data were from samples collected by capillary tube (i.e., droplets from a foot- or finger-prick). Samples collected prior to 2011 were analyzed by a fixed laboratory yielding a detection limit of 1 µg/dL and after 2011, samples were analyzed using a portable instrument that yielded a detection limit of 3 µg/dL. Each blood lead result is paired with gender, age, ethnicity, and residence location data. Summary statistics for the Butte-Silver Bow County blood lead database are provided in Table 4.

3.3.2 Flathead County, Montana

Flathead County, like Silver Bow County, is classified as having a services-dependent economy. Approximately 91,000 people reside in Flathead County and 19,700 of whom reside in micropolitan statistical area of Kalispell. As shown in Table 2, similar proportions (6 percent) of residents in Flathead and Silver Bow Counties are under the age of 5 years. A slightly higher proportion (92 percent) of Flathead residents has earned their high school diploma or equivalency than in Silver Bow County (90 percent). Flathead's annual per capita income of $25,300 is greater than that of Silver Bow, which also has a greater proportion of residents living below the federal poverty level (16 percent in Silver Bow compared to 13 percent in Flathead).

Flathead County is designated as both a housing stress and nonmetropolitan recreation area; designations which may be inter-related in that the sub-standard housing conditions may be attributable to recreational homes (see Table 1). As shown in Table 3, Kalispell itself has newer housing stock than Butte, with 51 percent of the total housing (9,100 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. Although Kalispell has a higher percentage of non-owner occupied housing (42 percent), the housing stock is younger and, therefore, less likely to present risks from historic lead sources (i.e., paint, plumbing).

The Flathead County Community Health Services Department advertises on-going, free lead screening of capillary blood samples, but blood lead data are not readily accessible (White and Stouts 2013).

Kalispell's Northwest Montana Head Start Program tests all children for BLLs and maintains some records in an electronic database. The program's Health and Nutrition Manager shared 199 de-identified, individual capillary data collected for years 2010 and 2011 (Napier 2013). However, individual results do not include the age or gender of the child, only date of sample collection and analytical result (detection limit of 1 µg/dL). Blood lead data collected prior to 2010 was collected, but the data is not readily available in a useable format.

Strengths of Kalispell-Flathead County as a reference population include:

- Similar education, median income, and poverty level,
- Similar services-based economy,
- No known major industrial point-sources of lead.

Weaknesses of Kalispell-Flathead County as a reference population include:

- Younger total population than in Butte but this is not expected to impact BLL comparisons for children under age 5 years, Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available blood lead data from Northwest Montana Head Start for 2010 and 2011 are not consistent with Butte study time-frame and do not include age and gender associated with individual results,
- Northwest Montana Head Start blood lead data collected prior to 2010 is archived, but not available in a useable format for external use.

3.3.3 Gallatin County, Montana

Gallatin County has a government-dependent economy, in contrast to the services-dependent economies of both Silver Bow and Flathead Counties. Approximately 90,000 people reside in Gallatin County, 37,000 people of whom reside in the micropolitan of Bozeman. Similar to Butte, five percent of Bozeman's residents are under the age of five years, as shown in Table 2. Disparities in socioeconomics can be viewed in Table 2. For example, nearly all Gallatin County residents (96 percent) have earned their high school diploma or equivalency compared to 90 percent in Silver Bow. Also, Gallatin's annual per capita income of $27,800 exceeds that of Silver Bow and 13 percent of Gallatin residents live below the poverty level, compared to 16 percent in Silver Bow.

Gallatin County is classified as a housing stress area by ERS. It is possible that the housing stress designation is correlated with its designation as a nonmetropolitan recreation county, where rudimentary recreational homes (i.e., cabins) may be common (see Table 1). As shown in Table 3, Bozeman itself has a much newer housing stock than Butte, with only 44 percent of the total housing (16,900 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. Although Bozeman has a higher percentage of non-owner occupied housing (55 percent), the housing stock is younger and may be less likely to present risks from historic lead sources (i.e., paint, plumbing).

The Human Resource Development Council (HRDC) provides Head Start educational services to low-income children ages 3 to 5 years in Gallatin, Park, and Meagher Counties. As part of HRDC's educational services, blood lead screening is conducted annually. For the past four to five years, HRDC has used the LeadCare II system for screening enrolled children; prior to that capillary testing was conducted. HRDC has indicated that they can provide BLL data for enrolled children, but data have not yet been received and years during which samples were collected is not yet known; conversations with HRDC are on-going (Origer 2013).

Strengths of Bozeman-Gallatin County as a reference population include:

- No known major industrial point-sources of lead,
- Blood lead data for children ages 3 to 6 years expected to be available from HRDC Head Start.

Weaknesses of Bozeman-Gallatin County as a reference population include:

- Differences in demographics and socioeconomics reflect younger population, higher income, and lower poverty rate than in Butte-Silver Bow,
- Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available Head Start blood lead data includes LeadCare II-analyzed data which are of limited utility.

3.3.4 Lewis and Clark County, Montana

Lewis and Clark County is home to the state capitol of Helena; the County is characterized by a government-dependent economy as opposed to a services-dependent economy. Approximately 63,400 people reside in Lewis and Clark County, 28,000 of whom live in the capital city of Helena. Like Silver Bow County, six percent of Lewis and Clark County residents are under the age of five years. Additional differences and similarities between demographic and socioeconomic characteristics can be viewed in Table 2. For example, 95 percent of Lewis and Clark residents have earned their high school diploma or equivalency compared to 90 percent in Silver Bow, and Silver Bow's annual per capita income is substantially lower than that of Lewis and Cark County.

The ERS does not classify Lewis and Clark County as a housing stress area. Approximately 70 percent of Helena's total housing stock (14,000 units) was constructed prior to the ban of lead in paint in the late 1970's, compared to Butte's 80 percent (Table 3). Further consideration of homes built prior to 1949, a period when lead content in paint was even greater than the period prior to 1979, reveals that roughly 30 percent of Helena's housing was constructed prior to 1949 compared to nearly 50 percent in Butte (Table 3). Thus, the age differences in Helena's housing stock compared with Butte's housing stock become more pronounced with consideration of pre-1950 housing. Helena has a greater percentage of non-owner occupied, and possibly less well-maintained, housing compared with Butte; however, on a county-level Lewis and Clark County has a lower percentage of non-owner occupied houses compared with Silver Bow County.

Blood lead data were collected from East Helena children age 6 months to 6 years for the years 1995 to 2011 in association with the East Helena Lead Education and Abatement Program (LEAP), which was established as part of the East Helena Superfund Site investigation and remediation effort. The blood lead data represent children living in an area impacted by a lead smelter that operated for well over 100 years, from 1888 to 2001. LEAP was established in 1995, the smelter closed in 2001, and lead abatement activities continued through 2010. U.S. EPA reports that BLLs have declined since the program's inception (USEPA 2013b). Prior to 1985, BLLs in only one-third of the children were below 10 µg/dL, whereas during the period 2000 to 2004 BLLs in 97 percent of children were at or below 4 µg/dL (USEPA 2013b).

De-identified LEAP blood lead data for all program years 1995 to 2011 are not available due to resource constraints preventing acquisition and transmittal of de-identified data[3]; however, de-identified data for approximately 140 children tested in September 2008 were readily available and provided by LEAP staff (Williams 2013). These data include BLL, age of child, date of blood test, and in some cases, yard soil lead levels or notes regarding date of yard soil remediation. The samples were collected using venous draws and depending on the laboratory conducting the analysis, the limit of detection is either 0.5 µg/dL or 2 µg/dL. Table 4 provides a summary of the September 2008 LEAP data, including age range, sample number, collection method, etc.

Strengths of Helena-Lewis and Clark County as a reference population include:

- Similar proportion of children below the age of 5,
- Similar housing stock age as for Butte, when considering homes constructed prior to 1979 but this similarity diminishes when considering pre-1950 construction,
- Blood lead data exists for East Helena children (up to 6 years) for years 2002 to 2011,
- De-identified, raw data for 140 children tested in 2008 have been provided by LEAP,
- Available blood lead data were analyzed in a fixed laboratory.

Weaknesses of Helena-Lewis and Clark County as a reference population include:

- Median income for Helena is 30% higher than in Butte and percentage of people living below poverty level is 3% lower, but these differences may not hold when focusing on East Helena community for whom we have blood lead data,
- 10% fewer owner-occupied homes, resulting in higher percentage of homes that are potentially less well-maintained than in Butte,
- Additional research may be needed to more clearly define socioeconomic and demographic characteristics of residents within the East Helena Superfund Site, represented by the LEAP BLL database,
- Blood lead database represents child population living within the area of influence of a former lead smelter,
- Blood lead database for entire program not available at this time (only 140 results from September 2008 available) due to resource limitations at LEAP / Lewis & Clark County Health Department.

3.3.5 Yellowstone County, Montana

Yellowstone County is a metropolitan county assigned an RUCC code of 3, representing metro areas of fewer than 250,000 people. The county population of 148,000 is dependent on a service-based economy similar to the Butte-Silver Bow area. Most of the county's residents, approximately 103,000 people, reside in Billings. The proportion of county residents under the age of 5 years (7 percent) is slightly higher than in Silver Bow County. As shown in Table 2, 92

[3] No annual summary reports describing number of samples analyzed each year were available. Much of the data is archived hard-copy, which would include patient name, address, etc.

percent of Yellowstone County residents have earned their high school diploma or equivalency compared to Silver Bow's 90 percent. Also, the annual per capita income is greater than that of Silver Bow and fewer of Yellowstone County's residents live in poverty (11 percent compared to Silver Bow's 16 percent).

ERS does not designate Yellowstone County as a housing stress area and Billings has newer housing stock than Butte, with 64 percent of the total housing (46,000 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. However, Billings and Butte have identical proportions of non-owner occupied housing (35 percent). Additional comparisons between the Billings-Yellowstone and Butte-Silver Bow areas can be made using data provided in Tables 2 and 3.

A brief report by the City of Billings regarding Head Start, Inc. blood lead testing of pre-school children indicated that few enrolled children are tested:

> "Head Start, Inc. has been performing lead-testing for children participating in their programs. In 2009, three of the 360 participating children were tested and all three were found to have no elevation in lead. Overall, the incidence of high BLLs in Montana children is 0.27%. The State stopped sending data to the Center for Disease Control in 2006 because there was no data to be sent. The data collected to date in Billings indicates that elevated lead blood levels are not a priority concern." -- in "*City of Billings Annual Action Plan, FY2011-2012, Year Two of the FY2010-2014 Consolidation Plan*" (no date)

Head Start, Inc. staff indicated that many children enrolled in their program are not tested by their physicians because they do not typically find children with elevated BLLs. As a consequence, the physicians do not view lead exposure as a current concern and consider the test unnecessary (McCulloch and Kelker 2013). Head Start, Inc. was willing to share de-identified data collected using LeadCare II from 2011 through 2013 by the Billings Clinic. An additional request for blood lead data collected prior to 2011 has been made, but it is not known if older data are available and if they were collected using LeadCare II or other methods.

Strengths of Billings-Yellowstone County as a reference population include:

- Similar services-based economy,
- No known major industrial point-sources of lead.

Weaknesses of Billings-Yellowstone County as a reference population include:

- Larger population may reflect greater urban area sources of lead than in Butte,
- Dissimilar income and poverty levels and other socioeconomic characteristics,
- Newer housing stock is not comparable to distribution of home ages in Butte-Silver Bow County,
- Available blood lead data for Head Start-enrolled children was collected outside the Butte Health Study time-frame and data quality for LeadCare II results is inadequate for use in the study.

3.3.6 Lake County, Colorado

Lake County is a micropolitan area (USDA 2013). Unlike other areas considered, Lake County is assigned a nonspecialized economic dependence RUUC code of 6 (USDA 2013). As shown in Table 2, the urbanization level, demographic, and socioeconomic characteristics of Lake County differ from Silver Bow. For example, the proportion of children under age 5 is 8 percent of the total population, compared to Silver Bow's 6 percent. Also, Lake County's population has a lower (81 percent) educational attainment level than Silver Bow (90 percent) with regard to obtaining a high school diploma or equivalent; although, Lake County's median household and per capita income are nearly identical to that of Silver Bow.

Lake County is designated by ERS as a housing stress area, perhaps due to the presence of recreational homes in surrounding wilderness areas, which would be consistent with the ERS designation as a nonmetro recreation county. As shown in Table 3, Lake County has similarly-aged housing stock as the Butte-Silver Bow area, with 75 percent of the total housing units (4,117 units) constructed prior to the ban of lead in paint in the late 1970's compared to Butte's 80 percent. When considering homes built prior to 1950, the proportion of Lake County's housing stock in that category is less (40 percent) than that of Butte-Silver Bow (50 percent). Also, Lake County has a similar proportion of non-owner occupied housing (33 percent) as Butte (35 percent).

Lake County is home to Leadville, a historic mining district where the California Gulch Superfund Site is located. Mining impacts have resulted in elevated soil lead levels in residential areas. Nevertheless, data from Lake County were pursued for possible consideration as a reference dataset and annual summary data for the period from 2006 to 2010 for children ages 12 to 72 months were obtained from the county health department,.

A blood lead monitoring program operated by Lake County Health Department was established in 1995 as part of the cleanup agreement for the California Gulch Superfund Site. At that time, the estimated population of Lake County was approximately 6,000, with half of the population residing within Leadville. In 1991, prior to site remediation, a blood lead survey involving 314 children (64 percent of child population) demonstrated that the site-wide geometric mean BLL for Leadville children was 5 to 6 µg/dL, with 8 percent of children exceeding the CDC threshold of 10 µg/dL (USEPA 1999). Between 1999 and 2005, as part of the site cleanup agreement for residential soils, the Lake County Community Health Program worked to reduce soil lead exposures among child residents through its "Kids First" blood lead monitoring and education program. By 2005, the program had achieved its performance goals, but was extended to reduce overall lead exposure through continued education and blood lead monitoring (Lake County Board of County Commissioners 2009).

Individual de-identified blood lead data for child residents of Leadville are not available, but summary data have been obtained for years 2006 through 2010 (Lake County Public Health Agency 2013). Summary data include number of initial and re-tested children ages 12 months to 6 years and average and maximum BLLs for initial and re-test, by year and study area. A summary of all areas combined, by year, is provided in Table 3. All initial tests were conducted using capillary blood samples, re-test results for capillary results greater than 10 µg/dL are based on venous blood draws (Patti 2013).

Strengths of Leadville-Lake County as a reference population include:

- Similar proportion of housing constructed prior to 1979 compared to Butte-Silver Bow; this relationship generally holds for homes built prior to 1950,
- Summary blood lead data are available for children ages 1 to 6 six years,
- Blood lead data were analyzed via fixed laboratory,
- Available summary data were collected within Butte study period.

Weaknesses of Leadville-Lake County as a reference population include:

- Urbanization level and demographic and socioeconomic characteristics differ from those of Butte-Silver Bow,
- Community is located within a mining district with elevated levels of lead in soil,
- Individual blood lead data are not available.

3.3.7 Shoshone County, Idaho

Shoshone County, a nonmetropolitan county, is located in northern Idaho and is assigned an ERS RUCC code of 1 representing a farming-dependent economy (USDA 2009). Shoshone County's population is approximately 13,000, 5 percent of whom are under the age of 5 years. As shown in Table 2, fewer of Shoshone County's residents (82 percent) have earned a high school diploma or equivalent compared to Silver Bow County (90 percent). The per capita income in Shoshone County is slightly lower, reflected also in a slightly greater higher poverty rate.

Shoshone County is not classified as an ERS housing stress area, similar to Silver Bow County, and similar proportions of housing were constructed prior to 1979 though a greater proportion of Shoshone County homes are owner-occupied (see Table 3). The proportion of housing stock built prior to 1950 in Shoshone County is less (40 percent) than that of Butte-Silver Bow (50 percent).

Shoshone County contains the Coeur d'Alene River Basin, which is home to the Bunker Hill Mining and Metallurgical Superfund Site. The site was listed in 1983 due to metals contamination from historic mining activities, and is divided into three areas, the Coeur d'Alene Basin, a 21-mile square "Bunker Hill Box" which includes the populated areas, the non-populated areas of the Bunker Hill Box, and the Coeur d'Alene Basin which includes areas outside of the Box. Lead contamination resulting from historical mining practices led to blood lead monitoring of site residents since the mid-1980's through the Lead Health Intervention Program (LHIP). Summary data for children ages 6 to 72 months of age tested through the LHIP are available for years 2002 to 2010 (PHD 2008, 2009, 2010, 2012). Individual data are stored and managed on behalf of the LHIP by a private company, which must be contracted with directly for data analyses. Data are not stored in a de-identified format that facilitates sharing with outside entities.

Strengths of Coeur d'Alene Basin-Shoshone County as a reference population include:

- Similar proportion of homes constructed prior to 1979 compared to Butte-Silver Bow; this relationship generally holds for homes built prior to 1950,
- Summary blood lead data are available for children ages 6 months to 6 six years,
- Blood lead data were analyzed via fixed laboratory,
- Available summary data were collected within Butte study period.

Weaknesses of Coeur d'Alene Basin-Shoshone County as a reference population include:

- Urbanization level and demographic and socioeconomic characteristics differ from those of Butte-Silver Bow,
- Community is located within a mining district with elevated levels of lead in soil,
- Individual blood lead data cannot be directly accessed because they are not stored in a de-identified format that protects the privacy of the sampled individuals.

Table 1: ERS Rural-Urban Continuum Code and County Typology Codes

State-County FIPS Code	County, State	NCHS Classification	2013 Rural-urban Continuum Code (a)	Economic-dependence County Indicator (b)	Housing Stress County Indicator (c,d)	Nonmetro Recreation County Indicator (c, e)
30093	Silver Bow County, MT	Micropolitan	5	5	0	0
30029	Flathead County, MT	Micropolitan	5	5	1	1
30031	Gallatin County, MT	Micropolitan	5	4	1	1
30041	Hill County, MT	Micropolitan	7	6	0	0
30043	Jefferson County, MT	Micropolitan	9	2	0	0
30049	Lewis and Clark County, MT	Micropolitan	5	4	0	0
30111	Yellowstone County, MT	Small metro	3	5	0	0
08065	Lake County, CO	Micropolitan	7	6	1	1
16079	Shoshone County, ID	Noncore	7	1	0	0

Source: NCHS 2012; USDA 2009, 2013

Notes:

(a) Also known as the Beale Code. 3=County in metro area of fewer than 250,000 population; 5=Nonmetro county with urban population of 20,000 or more, not adjacent to a metro area; 7=Nonmetro county with urban population of 2,500-19,999, not adjacent to a metro area; 9=Completely rural or less than 2,500 urban population, not adjacent to a metro area

(b) 1=Farming-dependent 2=Mining-dependent 3=Manufacturing-dependent 4=Federal/State government-dependent 5=Services-dependent 6=Nonspecialized

(c) 0=no 1=yes

(d) Housing stress (537 total, 302 nonmetro) counties--30 percent or more of households had one or more of these housing conditions in 2000: lacked complete plumbing, lacked complete kitchen, paid 30 percent or more of income for owner costs or rent, or had more than 1 person per room.

(e) Nonmetro recreation (334 designated nonmetro in either 1993 or 2003, 34 were designated metro in 2003) counties--classified using a combination of factors, including share of employment or share of earnings in recreation-related industries in 1999, share of seasonal or occasional use housing units in 2000, and per capita receipts from motels and hotels in 1997.

Table 2: U.S. Census Demographic and Socioeconomic Data

County, State	Population	White, non-Hispanic (one race)	% Male	% Female	Median Age	% Below Age 5 yrs	% Below Age 18 yrs	% Above Age 65 yrs	% High School Grad or Higher	% Bachelor Degree or higher	Per Capita Income	Median Household Income	% People Below Poverty Level
Focus Areas													
Silver Bow, MT	34,200	95	51	49	42	6	21	17	90	23	22,249	40,030	16
Flathead, MT	90,928	96	50	50	41	6	23	16	92	28	25,317	45,588	13
Gallatin, MT	89,513	96	52	48	32	6	21	10	96	45	27,769	51,391	13
Lewis and Clark, MT	63,395	94	49	51	41	6	22	15	95	37	27,121	53,053	10
Blood Lead Data-driven Focus Areas													
Yellowstone, MT	147,972	91	49	51	38	7	24	15	92	29	27,273	50,185	11
Lake, CO	7,010	74	52	48	35	8	25	8	81	22	21,063	40,543	30
Shoshone, ID	12,849	96	51	50	46	5	21	19	83	13	19,717	37,934	17
Micro or Metropolitan Centers within Focus Areas													
Butte, MT	32,982	95	51	50	42	5	21	16	91	23	22,421	40,485	16
Kalispell, MT	19,654	96	48	52	32	9	27	14	91	26	22,301	39,205	17
Bozeman, MT	37,070	93	54	47	27	5	15	8	97	52	25,699	44,412	20
Helena, MT	27,978	94	49	51	41	6	19	16	96	46	28,856	47,749	13

Table 2: U.S. Census Demographic and Socioeconomic Data

County, State	Population	White, non-Hispanic (one race)	% Male	% Female	Median Age	% Below Age 5 yrs	% Below Age 18 yrs	% Above Age 65 yrs	% High School Grad or Higher	% Bachelor Degree or higher	Per Capita Income	Median Household Income	% People Below Poverty Level
Micro or Metropolitan Centers within Blood Lead Data-driven Focus Areas													
Billings, MT	102,982	90	48	52	38	7	23	15	92	31	27,582	47,869	12
Lake, CO	7,010	74	52	48	35	8	25	8	81	22	21,063	40,543	30
Shoshone, ID	12,849	96	51	50	46	5	21	19	83	13	19,717	37,934	17
Source: U.S. Census 2013													

Table 3: U.S. Census Housing Data

County, State	% Owning Home	% Non-owner Occupied Housing	Total Housing Units	*Percent of Housing Constructed (by Year Grouping[a])*								
				2005 or later	2000-2004	1990-1999	1980-1989	1970-1979	1960-1969	1950-1959	1940-1949	1939 or earlier
Focus Areas												
Silver Bow, MT	66	35	16,675	2	3	8	7	11	8	12	7	42
Flathead, MT	72	29	48,141	8	12	19	16	18	7	7	5	7
Gallatin, MT	62	38	41,545	11	17	21	13	17	6	5	3	10
Lewis and Clark, MT	72	28	30,687	7	9	14	12	21	9	7	4	16
Blood Lead Data-driven Focus Areas												
Yellowstone, MT	70	30	63,345	5	8	12	14	22	9	14	6	9
Lake, CO	67	33	4,117	1	6	10	8	18	7	11	2	37
Shoshone County, ID	70	30	7,062	2	2	8	6	15	9	16	11	31
Micro or Metropolitan Centers within Focus Areas												
Butte, MT	65	35	16,243	2	3	9	7	11	8	12	7	41
Kalispell, MT	58	42	9,122	12	10	14	13	14	6	11	7	13
Bozeman, MT	45	55	16,857	14	17	14	11	14	7	7	5	12
Helena, MT	55	45	13,960	5	5	9	10	17	11	11	7	25
Micro or Metropolitan Centers within Blood Lead Data-driven Focus Areas												
Billings, MT	58	42	9,122	12	10	14	13	14	6	11	7	13
Lake, CO	67	33	4,117	1	6	10	8	18	7	11	2	37
Shoshone, ID	70	30	7,062	2	2	8	6	15	9	16	11	31

Source: U.S. Census 2013; [a] Year groupings as reported by source.

Table 4: Summary Information for Potential Reference Populations for which Publicly-Accessible Data are Available

Data Source	Date Range	Sample No.	Age Range (months)	DL	Collection Method	Related to Contaminated Site Monitoring?	Summary Data (Sum)/Raw Data (Raw)?	LeadCare (LC) vs Fixed Lab (Lab)
Focus Areas								
Butte Health Dept., Silver Bow County	2002-2011	3,274	12 – 60	1.0	Capillary	Yes	Raw	Lab
Kalispell Head Start, Flathead County	2010-2011	199	36 – 60	1.0	Capillary	No	Raw	Lab
Bozeman Head Start, Gallatin County	Unk	Unk	36 – 60	3.3	Capillary	No	Unk	LC / Unk
East Helena LEAP, Lewis & Clark County	2008	86	9 – 60	0.5, 2.0	Venous	Yes	Raw	Lab
Blood Lead Data-driven Focus Areas								
Billings Head Start, Yellowstone County	2011-2013	Unk	36 – 60	3.3	Capillary	No	Raw	LC
Lake County, CO	2006	377	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2007	349	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2008	321	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2009	375	12 – 72	Unk	Capillary	Yes	Sum	Lab
Lake County, CO	2010	332	12 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2002	368	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2007	8	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2008	18	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Box, Shoshone Co.	2009	18	6 mo – 9 yrs	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2002	103	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2003	75	6 – 72	Unk	Capillary	Yes	Sum	Lab

Table 4: Summary Information for Potential Reference Populations for which Publicly-Accessible Data are Available

Data Source	Date Range	Sample No.	Age Range (months)	DL	Collection Method	Related to Contaminated Site Monitoring?	Summary Data (Sum)/Raw Data (Raw)?	LeadCare (LC) vs Fixed Lab (Lab)
Bunker Hill, ID – Basin, Shoshone Co.	2004	80	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2005	81	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2006	69	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2007	71	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2008	73	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2009	175	6 – 72	Unk	Capillary	Yes	Sum	Lab
Bunker Hill, ID – Basin, Shoshone Co.	2010	108	6 – 72	Unk	Capillary	Yes	Sum	Lab

Notes:

Unk = unknown

NA = not applicable

4 Development of an NHANES-Based Reference Population

As noted by its name, the National Health and Nutrition Examination Survey (NHANES) is a program designed to assess the health and nutritional status of the U.S. population across all age groups. NHANES is a program within the National Center for Health Statistics, which is part of the Centers for Disease Control and Prevention.

The survey is administered in two-year cycles, with approximately 10,000 nation-wide participants selected for each survey. NHANES can be used to generate population based statistics for specific age groups, as well as for people self-identifying as being Hispanic and/or African American. The two-part survey includes an interview for all participants where demographic, socioeconomic, dietary, lifestyle and health-related questionnaires are administered. Almost all of the participants also participate in a physical examination where medical, dental, and physiological measurements are collected and laboratory analyses are performed on blood and urine samples.

In addition to BLLs, demographic and socioeconomic information is available for NHANES participants. The NHANES became a continuous program in 1999. Information collected from these surveys will be useful in understanding how the Butte community blood lead status compares to that of the rest of the United States, including: demographic information, health insurance status, housing age, income, and blood lead (age 1 year and older).

Strengths of using the NHANES dataset as a reference population include:

- Relevant time frame: Data from NHANES survey years 2001-2002, 2003-2004, 2005-2006, 2007-2008, 2009-2010 can be compiled for comparison with Butte 2002 – 2010 blood lead data,
- Large sample size: Two year sample size ranges from 723 children to 968 children, depending on the survey years,
- Appropriate age-range: Blood lead data represent people ages 1 through adult, allowing for selection of an age range and age distribution consistent with the Butte blood lead data collected among children up to age 6 years,
- High quality data: Venous sample collection with low detection limits allows accurate characterization of BLL distributions. The limit of detection was defined as 0.3 µg/dL in 1999-2000 and 2001-2002, 0.28 µg/dL in 2003-2004, and 0.25 µg/dL in 2005-2006, 2007-2008, and 2009-2010, which is lower than the limit of 1 µg/dL for the Butte blood lead data. The lower limits reported in the NHANES data may need to be adjusted for comparison with the Butte data. Several methods for adjustment of the NHANES data may be considered to reduce bias resulting from lower limits of detection and better align data with Butte analytical methods.

These key characteristics are summarized in Table 5.

Table 5: Summary Statistics for Selected NHANES 2-Year Survey Periods					
2-Year Survey Period	**Sample No.**	**Age Range (months)**	**Percent Detect**	**Collection Method**	**Summary Data (Sum) / Raw Data (Raw)?**
2003-2004	753	12 – 60	100	Venous	Raw
2005-2006	806	12 – 60	100	Venous	Raw
2007-2008	676	12 – 60	100	Venous	Raw
2009-2010	702	12 – 60	100	Venous	Raw

The NHANES dataset also includes critical information that may be adjusted to better match Butte dataset, including:

- Housing characteristics: House age data are linked to individual NHANES blood lead values, and are also available for individual values in the Butte dataset. House age is grouped by categories generally corresponding to changes in lead management policy, such as removal of lead from paint, gas, plumbing, solder in food containers, etc. House age groupings include: before 1940, 1940-1949, 1950-1959, 1960-1977, 1978-1989, and 1990-present. Representation from housing age groups may be matched to that of the wider Butte community.
- Socioeconomic and demographic data: Starting in 2001, NHANES contains the household and family income (as ranges) and a calculated poverty index ratio for the participants in the NHANES surveys. Poverty index, educational attainment of the reference individual for the household, race, health care status, age, and gender data are all available for the NHANES population. Of these factors only age and gender are available in the Butte dataset. Poverty level and race adjustments may be may on a census tract level, while educational attainment and health care status adjustments are not likely to be feasible.

Limitations of using the NHANES dataset as a reference population include:

- Lack of individual sample dates: Individual blood lead data are assigned to 6-month intervals, which may limit the ability to adjust for expected seasonal variation in BLLs.
- No identifying geographic data: Degree of urbanization for NHANES subject residences is not available in the public files. Because the survey method for NHANES is intended to be representative of the U.S. populations, blood lead data cannot be adjusted to represent rural micropolitan communities comparable to Butte.
- Sample selection bias: The volunteer NHANES population may have socioeconomic or other characteristics that are dissimilar from those of the Butte population.

A three step process has been used to determine if the NHANES database can be used to develop a dataset that can be used as a reference population for Butte: First data were selected by year and age range that matched Butte data. The matched sample periods extend from 2003 through 2010. The matched age ranges are 12 months through 60 months.

The second step involved a review and comparison of analytical methods and detection limits. NHANES analytical detection limits were 0.3 µg/dL in 1999-2000 and 2001-2002, 0.28 µg/dL in

2003-2004, and 0.25 µg/dL from 2005 through 2010, which resulted in few to no undetected values in the time period of interest. In contrast, the detection limit of 1 µg/dL for the Butte blood lead data resulted in 6% to 24% of the values being undetected (see Table 6). The lower limits reported in the NHANES data will need to be adjusted for comparison with the Butte data. Several methods for adjustment of the NHANES data are being considered to reduce bias resulting from lower limits of detection and better align data with Butte analytical methods. To align the NHANES and Butte datasets, non-detected values need to be treated comparably. Several methods for adjustment of the NHANES and/or Butte data may be considered to reduce bias resulting from differences in limits of detection. The non-detected values in the Butte dataset can be adjusted by imputing values below the detection limit, or by applying the NHANES rule[4] of replacing the detection limit with the detection limit divided by the square root of 2. Alternatively, all values less than 1 µg/dL in the NHANES dataset could be treated as non-detected values. These values could then be imputed or replaced by the detection limit divided by the square root of 2. A sensitivity analysis could be conducted to determine if the difference in detection limits is a significant factor in the dataset comparison and to guide development of appropriate adjustments.

Table 6: Comparison of Undetected Blood Lead Values for NHANES and Butte Datasets for Four Survey Periods

Dataset	2003-2004	2005-2006	2007-2008	2009-2010
NHANES	0 (0%)	0 (0%)	0 (0%)	1 (0.14%)
Butte	36 (5.6%)	42 (6.8%)	84 (13%)	187 (24%)

The third step included review of the feasibility of making adjustments to reflect differences in various independent variables between the two datasets. We considered age, gender, house age, race/ethnicity, seasons of sample collection, and indicators of poverty. As discussed above, gender has little influence on BLLs in young children, so even if the gender structure of the databases varies, it may not be necessary to make adjustments to align them according to gender. Other factors are described below.

- **Child age structure** – Figure 7 illustrates the child age structure by 6 month intervals for one two year period (2007-2008) of the two datasets. This figure shows that, during this two year period, the Butte dataset includes a higher proportion of children younger than 30 months. Because these children are expected to have higher BLLs than older children, the NHANES dataset will need to be adjusted to align with the Butte dataset age structure. Similar comparisons will be conducted for each survey period.

[4] In all NHANES laboratory data sets, non-detected results are not assumed to be present at the detection limit; non-detected results are assigned a value that is calculated as the lower limit of detection divided by the square root of 2. This substituted value is assumed to represent the midpoint of values falling below the limit of detection.

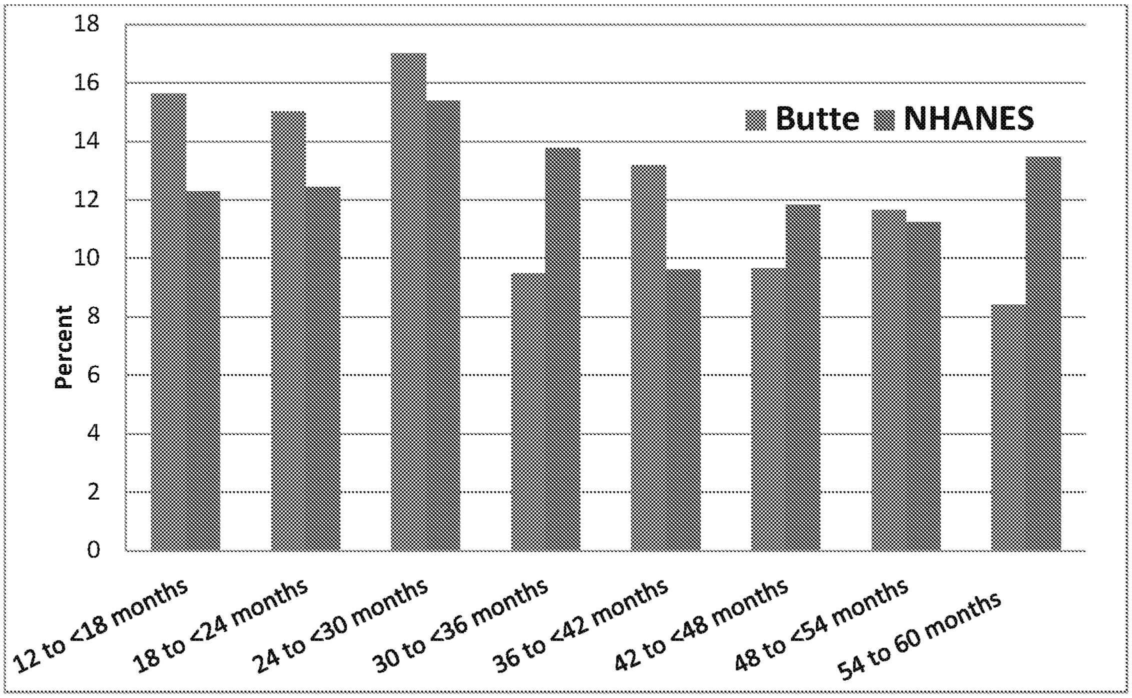


Figure 7. Child Age Structure Comparison for 2007-2008 Survey Period

- **House age** – Figure 8 shows a similar comparison (for the 2005-2006 period) of house age, based on NHANES home age categories. The Butte dataset for this period has a very high proportion of children who live in houses built before 1940 (close to 40%), whereas in the NHANES dataset less than 10% of the children live in such old houses.

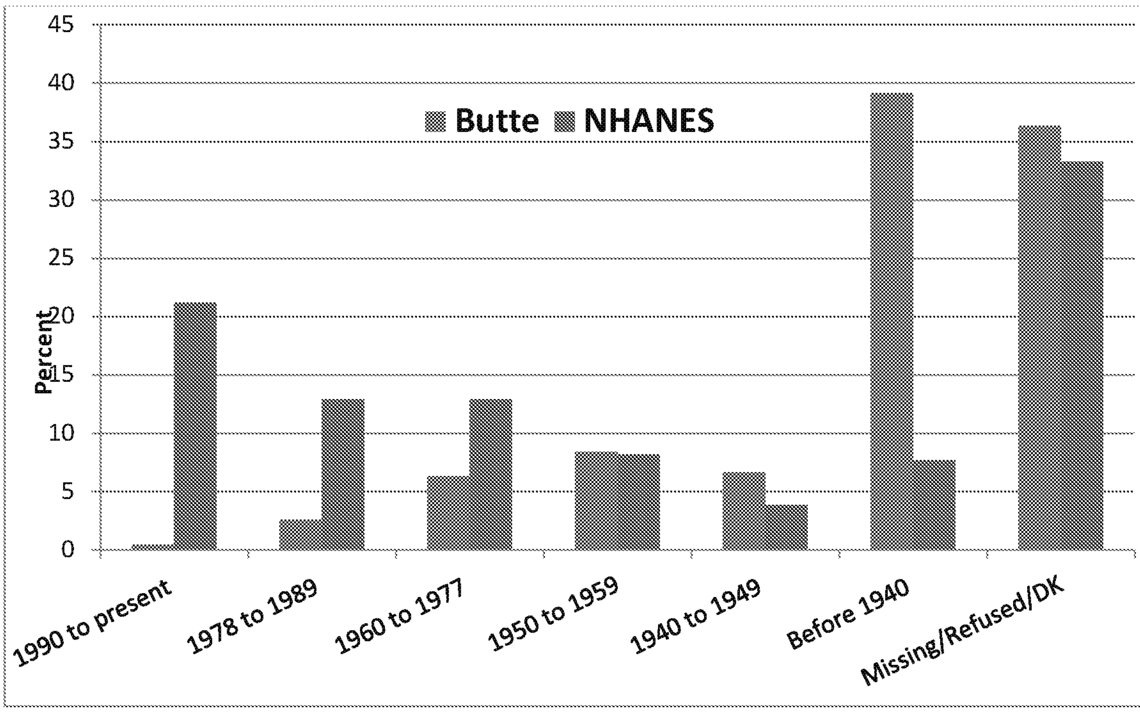


Figure 8. House Age Structure Comparison for 2005-2006 Survey Period

- **Racial/ethnic composition** – Figure 9 illustrates differences in racial/ethnic composition of the two datasets. The Butte dataset records do not indicate race, so a comparison was done by selecting two Butte census tracts. Butte's racial composition is predominantly non-Hispanic while, with very few non-Hispanic blacks.

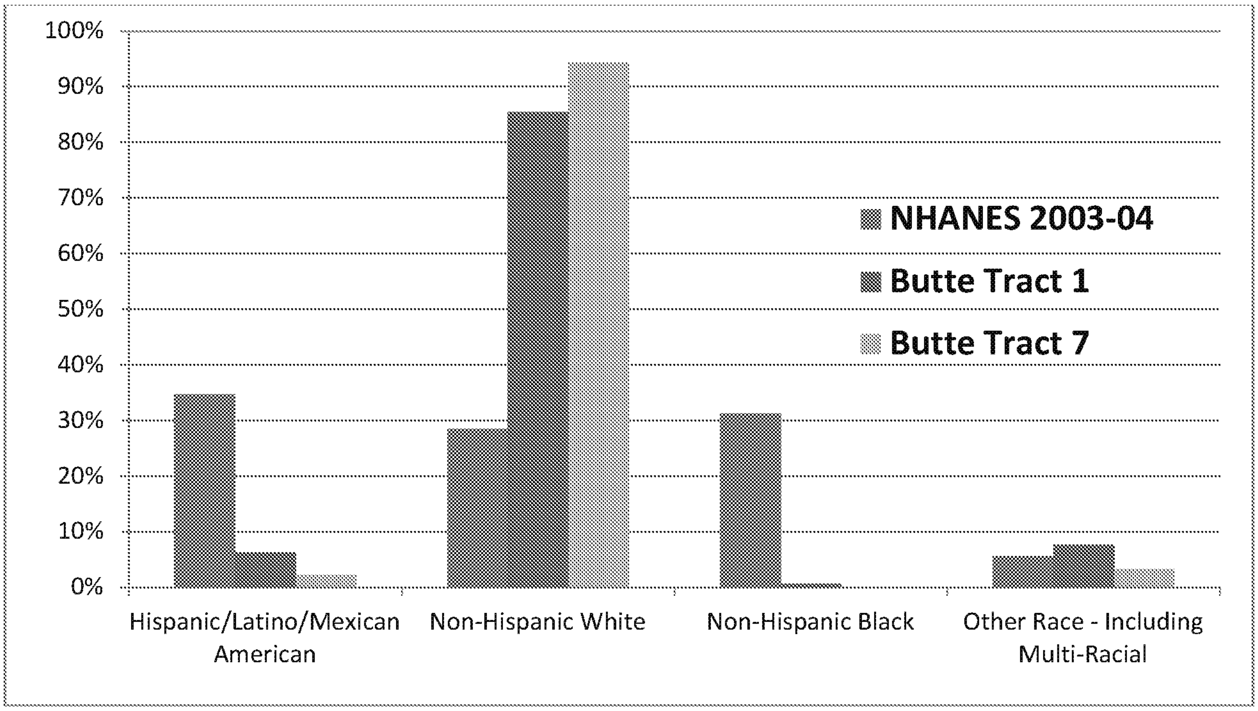


Figure 9. Race/Ethnicity Comparison for 2003-2004 Survey Period

- **Poverty status** – Poverty is another important factor for which the Butte dataset does not have individual records; but for which census tract level data are available. The Butte dataset is heavily weighted to children enrolled in Medicaid, thus biasing the dataset to children from low income families. Consequently, adjustments based on census tract poverty levels may not be valid.

- **Seasonal variations** – Sample dates are included in the Butte dataset, allowing for an analysis of variation in BLLs by season. As described above, preliminary analyses suggest that seasonal variation is an important factor affecting BLLs of Butte children. The NHANES dataset does not include specific sample dates, but samples are assigned to one of two 6 month periods extending from November through April and from May through October. The May through October period is consistent with the period when BLLs are highest, so that information will allow an examination of whether there are significant biases toward one season for another across the two datasets.

In summary, the NHANES dataset will allow for comparisons with the Butte dataset, both by age and by sample dates in six month to two-year increments. The blood lead data selected from the NHANES dataset can be matched to Butte community housing and economic characteristics, using available socioeconomic and housing information. The larger sample size of the NHANES dataset allows for selection of subsets of data that mirror the study years and age range associated with the Butte dataset while preserving sample sizes sufficient to conduct statistical comparisons of data that are also representative of other factors that influence BLLs.

Due to differences in demographics and other characteristics, NHANES blood lead data must be assigned weighting factors to more accurately mirror the Butte population. Applying weighting factors to demographic characteristics (i.e., age, race, gender) aligns NHANES and Butte population characteristics and would allow for use of NHANES data without having to discard any results. In this way, group size differences based on age, race and home age would not influence comparisons between populations. There would still be differences between the two datasets that we would not be able to adjust for, including the likelihood that data from samples collected by finger stick (Butte) would be biased higher than data from samples collected by venous (NHANES), and for reliance primarily on Medicaid enrolled children vs. a nationally representative population. Possible impacts of these residual differences would need to be explored in our analyses.

5 Recommended Reference Blood Lead Data

Based on the availability of a large dataset for the sample years and age ranges included in the Butte dataset, as well as the ability to correct for several factors that are strongly associated with BLLs, we are recommending use of the NHANES database for development of the reference population for Butte. While data collection efforts continue, no suitable comprehensive Montana reference dataset, nor dataset from other mountain states, has been identified to date. Further, experience to date indicates a low probability that any forthcoming data from such communities will provide a suitable reference dataset for use in the study.

The search for blood lead data from potentially comparable communities was a challenging exercise in that blood lead data often are limited or not available for communities with characteristics mostly closely aligned with those of Butte. When blood lead data are available, they typically are associated with Superfund remediation and intervention activities. While these databases may be more comprehensive than other community-based data and may provide some useful insights when compared with the Butte data, they cannot be used to assess how Butte BLLs compare with those of a reference population not affected by historical mining activities.

For many county health departments, staff responsible for supporting blood lead poisoning prevention programs is also responding to communicable disease outbreaks and other public health concerns. These many responsibilities combined with limited staff and funding resources, result in a reduced ability to organize, manage, and store blood lead data that is either collected by the health department or is reported to the health department by area physicians and laboratories. Even in cases where dedicated staff is available to manage blood lead programs, data often are not stored in a format that facilitates analysis and/or de-identification for protection of the sampled individual. For these reasons, acquisition of blood lead data from public health departments, other than Healthy Homes Study data collected using LeadCare System, was very limited.

Among the various data sources considered, Head Start programs appear to provide the most promising prospect for obtaining blood lead data. Federal regulations pertaining to Head Start funding (as well as WIC and Medicaid enrollment) have made testing a priority for many programs. However, Head Start staff often indicated that when children were referred to physicians for testing, the physicians were reluctant to administer the test because they do not view blood lead poisoning as a public health concern – even among Head Start-enrolled children. Head Start staff reports of a low rate of blood lead screening are consistent with findings of a May 2012 survey conducted by MDPHHS. Among Montana medical practitioners who responded to the mail-in survey, less than 28 percent reported that they routinely test Medicaid enrolled children ages 1 to 5 years for lead, 61 percent test only when risk factors[5] are present, and 21 percent of practitioners do not test for lead (MDPHHS 2012). Reasons listed for not performing the required lead screening included a perceived low level of lead exposure in their geographic area and parental refusal of testing (MDPHHS 2012). Nevertheless, some programs appear to be persevering in testing enrolled children for lead exposure and have

[5] Age of child's current home, zip code, address of previous child residence, and standardized assessment questionnaire are factors used by practitioners to determine child's risk for lead exposure.

agreed to provide de-identified data (conversations are on-going; data are expected in early August 2013). However, these data will represent children ages 3 to 6 years. Methods for testing and analysis vary, so it is not yet known if data that do become available would meet data quality requirements for use in the Butte Health Study.

Additionally, in some cases, Head Start and public health programs are using the LeadCare system for on-site capillary blood analysis. This system provides instantaneous results but the limit of detection is not acceptable for use in Butte Health Study analyses. As we continue to follow-up on inquiries for blood lead data, we may find that much of the recent data is not useable because of the increased use of the LeadCare system to screen for blood lead poisoning.

In contrast to the limited and/or uncertain potential for available blood lead data from community sources with characteristics comparable to the Butte blood lead dataset, the NHANES database provides a large blood lead dataset corresponding to the sample years and age ranges included in the Butte dataset. Further, the NHANES database affords the ability to correct for several factors that are strongly associated with BLLs as discussed in sections 2.1 and 2.2. Potential limitations of the NHANES database for comparisons to the Butte data relate to differences between the two datasets for which adjustments are not feasible. For instance, while studies of simultaneous collection of venous and capillary blood lead samples have shown good correlation, capillary blood lead samples may be prone to more external contamination than venous resulting in concentrations that are biased high in comparison to venous. Because the NHANES blood lead data have been collected by venous sampling and the Butte data by capillary sampling, it is possible that blood lead concentrations for the Butte data will be biased high relative to the NHANES data, independent of other factors that might influence blood lead distributions. Similarly, differences between NHANES and Butte with respect to drivers for participant enrollment are also not feasible to account for, but may influence comparability of the two datasets. The Butte participant pool is largely comprised of WIC clients and/or Medicaid enrolled children in contrast to the NHANES survey population which is more likely to include a broader sampling of individuals. As with the sampling differences, participant enrollment differences are also likely to conservatively bias the Butte data high relative to the NHANES data. While the influence of these factors will be important to consider when interpreting statistically significant differences between the Butte and the reference dataset, the potential bias toward higher Butte blood lead concentrations is not outweighed by all of the other strengths associated with use of the NHANES database as detailed in section 4.

Based on all of the above considerations, we recommend use of the NHANES database for development of the reference blood lead dataset for primary use in comparison to Butte blood lead data in the Butte Health Study. Additional comparative analyses using subsets of some of the other reference data sources identified may also be useful for interpreting the distribution of BLLs in Butte and these will be considered further as development of proposed statistical approaches for use in the Butte health study proceeds.

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